

## ATTENT COOPERATION TRITY

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF THE RECORDING  
OF A CHANGE(PCT Rule 92bis.1 and  
Administrative Instructions, Section 422)

Date of mailing (day/month/year) 20 July 1999 (20.07.99)
Applicant's or agent's file reference 970M 1412WOP
International application No. PCT/IB97/01634

To:
KAMPFENKEL, Klaus Blumbach Kramer & Partner GbR Alexandrastrasse 5 D-65187 Wiesbaden ALLEMAGNE

1. The following indications appeared on record concerning: <input type="checkbox"/> the applicant <input type="checkbox"/> the inventor <input type="checkbox"/> the agent <input type="checkbox"/> the common representative				
Name and Address  HERDEN, Andreas Blumbach Kramer & Partner GbR Sonnenberger Strasse 100 D-65193 Wiesbaden Germany	State of Nationality		State of Residence	
	Telephone No. 0611/956870			
	Facsimile No. 0611/9568724			
	Teleprinter No.			
2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning: <input checked="" type="checkbox"/> the person <input type="checkbox"/> the name <input checked="" type="checkbox"/> the address <input type="checkbox"/> the nationality <input type="checkbox"/> the residence				
Name and Address  KAMPFENKEL, Klaus Blumbach Kramer & Partner GbR Alexandrastrasse 5 D-65187 Wiesbaden Germany	State of Nationality		State of Residence	
	Telephone No. 0611/956870			
	Facsimile No. 0611/9568724			
	Teleprinter No.			
3. Further observations, if necessary: The new address for correspondence on the demand has been considered as a change under Rule 92bis. In case of disagreement, the applicant should notify the International Bureau immediately.				
4. A copy of this notification has been sent to: <input checked="" type="checkbox"/> the receiving Office <input type="checkbox"/> the designated Offices concerned <input type="checkbox"/> the International Searching Authority <input checked="" type="checkbox"/> the elected Offices concerned <input checked="" type="checkbox"/> the International Preliminary Examining Authority <input type="checkbox"/> other:				

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland  Facsimile No.: (41-22) 740.14.35	Authorized officer  Jocelyne Rey-Millet  Telephone No.: (41-22) 338.83.38
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## TENT COOPERATION TRE.

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF ELECTION  
(PCT Rule 61.2)

To:

United States Patent and Trademark  
Office  
(Box PCT)  
Crystal Plaza 2  
Washington, DC 20231  
ÉTATS-UNIS D'AMÉRIQUE

in its capacity as elected Office

Date of mailing (day/month/year) 20 July 1999 (20.07.99)
International application No. PCT/IB97/01634
International filing date (day/month/year) 17 October 1997 (17.10.97)
Applicant RUDIN, Vsevolod Nikolaevich et al

Applicant's or agent's file reference  
970M 1412WOP

Priority date (day/month/year)

1. The designated Office is hereby notified of its election made:

in the demand filed with the International Preliminary Examining Authority on:

17 May 1999 (17.05.99)

in a notice effecting later election filed with the International Bureau on:

2. The election  was

was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

BEST AVAILABLE COPIE

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No.: (41-22) 740.14.35	Authorized officer Jocelyne Rey-Millet Telephone No.: (41-22) 338.83.38
---	---

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

PCT

<p>To:  <b>ZWIRNER, Gottfried</b>  <b>Sonnenberger Strasse 100</b>  <b>65193 Wiesbaden</b>  <b>GERMANY</b></p>		<p><b>PATENTCONSULT</b>  <b>WIESBADEN</b></p> <p>NOTIFICATION OF TRANSMITTAL OF          THE INTERNATIONAL SEARCH REPORT          OR THE DECLARATION</p> <p><b>20. Juli 1998</b></p> <p>(PCT Rule 44.1)</p>	
		<p>FRIST TERM</p>	<p>ERL. NOT.</p>
		<p>Date of mailing (day/month/year)</p> <p><b>16/07/1998</b></p>	
<p>Applicant's or agent's file reference  <b>970M 1412WOP</b></p>		<p><b>FOR FURTHER ACTION</b> See paragraphs 1 and 4 below</p>	
<p>International application No.  <b>PCT/IB 97/01634</b></p>		<p>International filing date (day/month/year)</p> <p><b>17/10/1997</b></p>	
<p>Applicant  <b>ZAKRYTOE AKTSIONERNOE OBSCHESTVO "OSTIM" et al.</b></p>			

1.  The applicant is hereby notified that the International Search Report has been established and is transmitted herewith.

**Filing of amendments and statement under Article 19**

The applicant is entitled, if he so wishes, to amend the claims of the International Application (see Rule 46):

**When?** The time limit for filing such amendments is normally 2 months from the date of transmittal of the International Search Report; however, for more details, see the notes on the accompanying sheet.

**Where?** Directly to the International Bureau of WIPO  
 34, chemin des Colombettes  
 1211 Geneva 20, Switzerland  
 Facsimile No.: (41-22) 740.14.35

For more detailed instructions, see the notes on the accompanying sheet.

2.  The applicant is hereby notified that no International Search Report will be established and that the declaration under Article 17(2)(a) to that effect is transmitted herewith.

3.  With regard to the protest against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.

no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Further action(s):** The applicant is reminded of the following:

Shortly after 18 months from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90bis.1 and 90bis.3, respectively, before the completion of the technical preparations for international publication.

Within 19 months from the priority date, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until 30 months from the priority date (in some Offices even later).

Within 20 months from the priority date, the applicant must perform the prescribed acts for entry into the national phase before all designated Offices which have not been elected in the demand or in a later election within 19 months from the priority date or could not be elected because they are not bound by Chapter II.

<p>Name and mailing address of the International Searching Authority</p> <p>European Patent Office, P.B. 5818 Patentlaan 2          NL-2280 HV Rijswijk          Tel. (+31-70) 340-2040, Tx. 31 651 epo nl.          Fax: (+31-70) 340-3016</p>	<p>Authorized officer</p> <p><b>Claudia Aragone</b></p>
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## PATENT COOPERATION TREATY

## PCT

## INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference <b>970M 1412WOP</b>	<b>FOR FURTHER ACTION</b> see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.	
International application No. <b>PCT/IB 97/ 01634</b>	International filing date (day/month/year) <b>17/10/1997</b>	(Earliest) Priority Date (day/month/year)
Applicant <b>ZAKRYTOE AKTSIONERNOE OBSCHESTVO "OSTIM" et al.</b>		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 2 sheets.

It is also accompanied by a copy of each prior art document cited in this report.

1.  Certain claims were found unsearchable (see Box I).
2.  Unity of invention is lacking (see Box II).
3.  The international application contains disclosure of a nucleotide and/or amino acid sequence listing and the international search was carried out on the basis of the sequence listing
  - filed with the international application.
  - furnished by the applicant separately from the international application.
    - but not accompanied by a statement to the effect that it did not include matter going beyond the disclosure in the international application as filed.
  - Transcribed by this Authority
4. With regard to the title,  the text is approved as submitted by the applicant
  - the text has been established by this Authority to read as follows:
5. With regard to the abstract,
  - the text is approved as submitted by the applicant
  - the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this International Search Report, submit comments to this Authority.
6. The figure of the drawings to be published with the abstract is:
 

Figure No. \_\_\_\_\_

  - as suggested by the applicant.
  - because the applicant failed to suggest a figure.
  - because this figure better characterizes the invention.
  - None of the figures.

# INTERNATIONAL SEARCH REPORT

I	International Application No
	97/01634

A. CLASSIFICATION OF SUBJECT MATTER

IPC 6 A61K7/16

According to International Patent Classification(IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category :	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 786 245 A (SANGI CO., LTD) 30 July 1997 see the whole document ---	1-10
X	EP 0 664 133 A (AKTIONERNOE OBSCHESTVO ZAKRYTOGO TIPIA "OSTIM") 26 July 1995 see claim 1; example 1 ---	1
E	WO 98 18719 A (AKTSIONERNOE OBSCHESTVO ZAKRYTOGO TIPIA "OSTIM") 7 May 1998 see claims 1,14 -----	1

Further documents are listed in the continuation of box C.

Patent family members are listed in annex.

\* Special categories of cited documents :

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

Date of mailing of the international search report

9 July 1998

16/07/1998

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2  
NL - 2280 HV Rijswijk  
Tel. (+31-70) 340-2040, Tx. 31 651 apo nl.  
Fax: (+31-70) 340-3016

Authorized officer

Glikman, J-F

## PATENT COOPERATION TREATY

PCT

REC'D 18 JAN 2000  
WIPO PCT

17

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 970M 1412WOP	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/IB97/01634	International filing date (day/month/year) 17/10/1997	Priority date (day/month/year) 17/10/1997
International Patent Classification (IPC) or national classification and IPC A61K7/16		
Applicant ZAKRYTOE AKTSIONERNOE OBSCHESTVO "OSTIM" et al.		
<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 4 sheets, including this cover sheet.</p> <p><input checked="" type="checkbox"/> This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of 3 sheets.</p>		
<p>3. This report contains indications relating to the following items:</p> <ul style="list-style-type: none"> <li>I <input checked="" type="checkbox"/> Basis of the report</li> <li>II <input type="checkbox"/> Priority</li> <li>III <input type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</li> <li>IV <input type="checkbox"/> Lack of unity of invention</li> <li>V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</li> <li>VI <input checked="" type="checkbox"/> Certain documents cited</li> <li>VII <input type="checkbox"/> Certain defects in the international application</li> <li>VIII <input type="checkbox"/> Certain observations on the international application</li> </ul>		

Date of submission of the demand 17/05/1999	Date of completion of this report 14.01.00
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Kardas-Llorens, E Telephone No. +49 89 2399 8652



INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT

International application No. PCT/IB97/01634

**I. Basis of the report**

1. This report has been drawn on the basis of (substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments.):

**Description, pages:**

2-9 as originally filed

1 as received on 17/11/1999 with letter of 17/11/1999

*faa*

**Claims, No.:**

1-10 as received on 17/11/1999 with letter of 17/11/1999

*faa*

2. The amendments have resulted in the cancellation of:

the description, pages:  
 the claims, Nos.:  
 the drawings, sheets:

3.  This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

4. Additional observations, if necessary:

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

**1. Statement**

Novelty (N) Yes: Claims 1-3, 9, 10

No: Claims 4-8

Inventive step (IS) Yes: Claims 1-3, 9, 10

No: Claims

Industrial applicability (IA) Yes: Claims 1-10

No: Claims

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT**

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International application No. PCT/IB97/01634

2. Citations and explanations

**see separate sheet**

**VI. Certain documents cited**

1. Certain published documents (Rule 70.10)

and / or

2. Non-written disclosures (Rule 70.9)

**see separate sheet**

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/IB97/01634

**Re Item V**

**Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

Reference is made to the following documents:

D1: EP-A-0786245

D2: EP-A-0664133

**Novelty:**

A hydroxyapatite composition with a specific surface as presently claimed in claim 4 is disclosed in D2 (see in particular claim 1 and column 8, l. 45-47 in D2).

Claim 4 is directed to a composition, thus, the intended purpose is disregarded for determining novelty. Besides the above decisive fact, attention is drawn to column 1, l. 5 which indicates the relation of the invention in D2 to surgical stomatology.

D1 discloses dental compositions comprising HAP having a particle size in a range from 0,05 to 1.0 micrometer. Even if the presently claimed specific surface is not disclosed in D1, the HAP having the above particle size, might lead to HAP having a surface which might fall into the presently claimed surface range.

**Inventive Step:**

The stimulation of active preventive treatment of the inflammable-destructive diseases such as paradenitis and paradentosis due to the specific shape of the HAP as claimed in claim 1 has not been taught either by D1 or by D2.

**Re Item VI**

**Certain documents cited**

(Rule 70.10)

Application No Patent No	Publication date (day/month/year)	Filing date (day/month/year)	Priority date (valid claim) (day/month/year)
WO 98/18719	07.05.98	29.10.97	31.10.96

The content of the above document destroys the novelty of the subject-matter of present claim 4.

No check has been made as to whether the priority of the above document has been validly claimed.

Ostim

## STOMATIC COMPOSITION

DescriptionField of the Invention

This invention relates to the field of medicine, and in particular to the field of stomatology and may be used for preventive treatment and curing of caries, parodontitis and paradentosis.

Prior art

For these above-captioned purposes, stomatic compositions comprising hydroxyapatite (HA) have found an extensive application in the stomatologic practice.

There are certain compositions having a favourable effect including synthetic HA containing 92 to 97%  $\text{Ca}_{10}(\text{PO}_4)_6(\text{OH})_2$ , 3 to 6%  $\text{H}_2\text{O}$  and 0,3%  $\text{CaCO}_3$ , with an average particle size of 1 to 15 mm.

Such a stomatic composition, for instance, according to Patent EP 0344832 cl. A61K 7/16, comprises save the stated HA, water-soluble casein material or sodium trimetaphosphate, as an anti-caries agent and also other well known ingredients which depend upon the forms of the product manufactured, such as various humectants, binding thickeners, surfactants, flavouring agents.

The known stomatic composition (EP 0342726 03442715 cl. A61K 7/18, publ. 23.11.89) supplementary includes a fluorine-containing compound in the form of NaF or sodium monophluorophosphate as an anti-caries agent.

The amount of HA present in the stomatic composition is in the range of 1 to 50%, usually 2 to 20% by weight of the stomatic composition. The stomatic composition comprises some other ingredients: humectants, thickeners, surfactants

AMENDED SHEET

Ostim

Claims:

1. A ~~stematic~~-composition for stomatic applications characterised in that it comprises particles of hydroxyapatite with an average particle size in length (l), width (d) and thickness (h) of: l from ~~about~~ 0,2 mm to ~~about~~ 0,01 mm, d from ~~about~~ 0,1 mm to ~~about~~ 0,001, and h from ~~about~~ 0,1 mm to ~~about~~ 0,0001 mm.

2. The ~~stematic~~-composition according to claim 1 characterised in that it comprises particles of hydroxyapatite with an average particle size in length (l), width(d) and thickness(h) of ~~about~~ l = 0,06 mm +/- 50 %, d = 0,015 mm +/- 50 % and h = 0,005 mm +/- 50 %.

3. The ~~stematic~~-composition according to claim 1 characterised in that it comprises particles of hydroxyapatite with an average particle size in length (l), width(d) and thickness(h) of ~~about~~ l = 0,06 mm, d = 0,015 mm, h = 0,005 mm.

4. A ~~stematic~~-composition for stomatic applications characterised in that it comprises particles of hydroxyapatite having a specific surface of hydroxiapatite from ~~about~~ 100 m<sup>2</sup>/g to ~~about~~ 150 m<sup>2</sup>/g.

5. The ~~stematic~~-composition according to one of claims 1 to 4 characterized in that it comprises said hydroxyapatite particles ultra finely divided.

AMENDED SHEET

6. The composition according to one of claims 1 to 5 characterised in that the ultra finely divided hydroxyapatite particles are present in the composition in an amount of 0,1% to 50% by weight.

7. The composition according to one of claims 1 to 6 characterised in that the ultra finely divided hydroxyapatite is a synthetic hydroxyapatite which contains 99,9% of  $\text{Ca}_{10}(\text{PO}_4)_6(\text{OH})_2$ , by weight.

8. The composition according to one of claims 1 to 7 further characterised by at least one substance of the group consisting of

- humectants in a range from about 0% to 85% by weight,
- binders and thickeners a range of 0% to 10% by weight,
- abrasive materials in a range from 0.0% to 25%,
- Surfactants in a range from 0% to 5% by weight,
- Flavours in a range from 0% to 5% by weight.

9. The composition according to one of claims 1 to 8 further characterised by agents enhancing the gingivitis system of the mouth cavity and comprising extracts of natural plants including at least one of the group consisting of urtica, millefolium, chamomilla hypericum, salvia, etc. in the aqueous and in the aqueous-alcoholic form.

10. The composition according to one of claims 1 to 9 further characterised by antimicrobial and anti-plaque agents.

AMENDED SHEET

**PATENT COOPERATION TREATY**

From the  
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:		
ZWIRNER, Gottfried BLUMBACH, KRAMER & PARTNER GMBH Alexandrastrasse 5 D-65187 Wiesbaden ALLEMAGNE	PATENTCONSULT WIESBADEN	
		17. Jan. 2000
FRIST TERM	ERL. NOT.	

**PCT**

**NOTIFICATION OF TRANSMITTAL OF  
THE INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT**

(PCT Rule 71.1)

Applicant's or agent's file reference 970M 1412WOP	Date of mailing (day/month/year) 14.01.00	
<b>IMPORTANT NOTIFICATION</b>		
International application No. PCT/IB97/01634	International filing date (day/month/year) 17/10/1997	Priority date (day/month/year) 17/10/1997
Applicant ZAKRYTOE AKTSIONERNOE OBSCHESTVO "OSTIM" et al.		

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

**4. REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

Name and mailing address of the IPEA/ European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx. 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Bleeker, M Tel. +49 89 2399-8141	
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## PATENT COOPERATION TREATY

## PCT

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 970M 1412WOP	FOR FURTHER ACTION		See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/IB97/01634	International filing date (day/month/year) 17/10/1997	Priority date (day/month/year) 17/10/1997	
International Patent Classification (IPC) or national classification and IPC A61K7/16			
Applicant ZAKRYTOE AKTSIONERNOE OBSCHESTVO "OSTIM" et al.			
<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 4 sheets, including this cover sheet.</p> <p><input checked="" type="checkbox"/> This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of 3 sheets.</p>			
<p>3. This report contains indications relating to the following items:</p> <ul style="list-style-type: none"> <li>I <input checked="" type="checkbox"/> Basis of the report</li> <li>II <input type="checkbox"/> Priority</li> <li>III <input type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</li> <li>IV <input type="checkbox"/> Lack of unity of invention</li> <li>V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability: citations and explanations supporting such statement</li> <li>VI <input checked="" type="checkbox"/> Certain documents cited</li> <li>VII <input type="checkbox"/> Certain defects in the international application</li> <li>VIII <input type="checkbox"/> Certain observations on the international application</li> </ul>			
Date of submission of the demand 17/05/1999	Date of completion of this report 14.01.00		
Name and mailing address of the international preliminary examining authority:   European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer  Kardas-Llorens, E Telephone No. +49 89 2399 8652		

INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT

International application No. PCT/IB97/01634

I. Basis of the report

1. This report has been drawn on the basis of (substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments.):

Description, pages:

2-9 as originally filed

*fax*

1 as received on 17/11/1999 with letter of 17/11/1999

Claims, No.:

1-10 as received on 17/11/1999 with letter of 17/11/1999

*fax*

2. The amendments have resulted in the cancellation of:

the description. pages:  
 the claims. Nos.:  
 the drawings. sheets:

3.  This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

4. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N) Yes: Claims 1-3, 9, 10  
No: Claims 4-8

Inventive step (IS) Yes: Claims 1-3, 9, 10  
No: Claims

Industrial applicability (IA) Yes: Claims 1-10  
No: Claims

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT**

International application No. PCT/IB97/01634

**2. Citations and explanations**

**see separate sheet**

**VI. Certain documents cited**

**1. Certain published documents (Rule 70.10)**

**and / or**

**2. Non-written disclosures (Rule 70.9)**

**see separate sheet**

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/IB97/01634

**Re Item V**

**Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

Reference is made to the following documents:

D1: EP-A-0786245

D2: EP-A-0664133

Novelty:

A hydroxyapatite composition with a specific surface as presently claimed in claim 4 is disclosed in D2 (see in particular claim 1 and column 8, l. 45-47 in D2).

Claim 4 is directed to a composition, thus, the intended purpose is disregarded for determining novelty. Besides the above decisive fact, attention is drawn to column 1, l. 5 which indicates the relation of the invention in D2 to surgical stomatology.

D1 discloses dental compositions comprising HAP having a particle size in a range from 0,05 to 1.0 micrometer. Even if the presently claimed specific surface is not disclosed in D1, the HAP having the above particle size, might lead to HAP having a surface which might fall into the presently claimed surface range.

Inventive Step:

The stimulation of active preventive treatment of the inflammable-destructive diseases such as paradenitis and paradentosis due to the specific shape of the HAP as claimed in claim 1 has not been taught either by D1 or by D2.

**Re Item VI**

**Certain documents cited**

(Rule 70.10)

Application No Patent No	Publication date (day/month/year)	Filing date (day/month/year)	Priority date (valid claim) (day/month/year)
WO 98/18719	07.05.98	29.10.97	31.10.96

The content of the above document destroys the novelty of the subject-matter of present claim 4.

No check has been made as to whether the priority of the above document has been validly claimed.

422 Rec'd PCT/PTO 17 APR 2000

## STOMATIC COMPOSITION

DescriptionField of the Invention

This invention relates to the field of medicine, and in particular to the field of stomatology and may be used for preventive treatment and curing of caries, parodontitis and paradentosis.

Prior art

For these above-captioned purposes, stomatic compositions comprising hydroxyapatite (HA) have found an extensive application in the stomatologic practice.

There are certain compositions having a favourable effect including synthetic HA containing 92 to 97%  $\text{Ca}_{10}(\text{PO}_4)_6(\text{OH})_2$ , 3 to 6%  $\text{H}_2\text{O}$  and 0,3%  $\text{CaCO}_3$ , with an average particle size of 1 to 15  $\mu\text{m}$ .

Such a stomatic composition, for instance, according to Patent EP 0344832 cl. A61K 7/16, comprises save the stated HA, water-soluble casein material or sodium trimetaphosphate, as an anti-caries agent and also other well known ingredients which depend upon the forms of the product manufactured, such as various humectants, binding thickeners, surfactants, flavouring agents.

The known stomatic composition (EP 03442746 cl. A61K 7/18, publ. 23.11.89) supplementary includes a fluorine-containing compound in the form of NaP or sodium monophluorophosphate as an anti-caries agent.

The amount of HA present in the stomatic composition is in the range of 1 to 50%, usually 2 to 20% by weight of the stomatic composition. The stomatic composition comprises some other ingredients: humectants, thickeners, surfactants

Claims:

1. A stomatic composition characterised in that it comprises particles of hydroxyapatite with an average particle size in length (l), width (d) and thickness (h) of: l from about 0,2  $\mu\text{m}$  to about 0,01  $\mu\text{m}$ , d from about 0,1  $\mu\text{m}$  to about 0,001, and h from about 0,1  $\mu\text{m}$  to about 0,0001  $\mu\text{m}$ .

2. The stomatic composition according to claim 1 characterised in that it comprises particles of hydroxyapatite with an average particle size in length (l), width(d) and thickness(h) of about l = 0,06  $\mu\text{m}$  +/- 50 %, d = 0,015  $\mu\text{m}$  +/- 50 % and h = 0,005  $\mu\text{m}$  +/- 50 %.

3. The stomatic composition according to claim 1 characterised in that it comprises particles of hydroxyapatite with an average particle size in length (l), width(d) and thickness(h) of about l = 0,06  $\mu\text{m}$ , d = 0,015  $\mu\text{m}$ , h = 0,005  $\mu\text{m}$ .

4. A stomatic composition characterised in that it comprises particles of hydroxyapatite having a specific surface of hydroxiapatite from about 100  $\text{m}^2/\text{g}$  to about 150  $\text{m}^2/\text{g}$ .

5. The stomatic composition according to one of claims 1 to 4 characterized in that it comprises said hydroxyapatite particles ultra finely divided.

6. The composition according to one of claims 1 to 5 characterised in that the ultra finely divided hydroxyapatite particles are present in the composition in an amount of 0,1% to 50% by weight.

7. The composition according to one of claims 1 to 6 characterised in that the ultra finely, divided hydroxyapatite is a synthetic hydroxyapatite which contains 99,9% of  $\text{Ca}_{10}(\text{PO}_4)_6(\text{OH})_2$ , by weight.

8. The composition according to one of claims 1 to 7 further characterised by at least one substance of the group consisting of

- humectants in a range from about 0% to 85% by weight,
- bindings and thickeners a range of 0% to 10% by weight,
- abrasive materials in a range from 0.0% to 25%,
- Surfactants in a range from 0% to 5% by weight,
- Flavours in a range from 0% to 5% by weight.

9. The composition according to one of claims 1 to 8 further characterised by agents enhancing the gingivitis system of the mouth cavity and comprising extracts of natural plants including at least one of the group consisting of urtica, millefolium, chamomilla hypericum, salvia, etc. in the aqueous and in the aqueous-alcoholic form.

10. The composition according to one of claims 1 to 9 further characterised by antimicrobial and anti-plaque agents.

## PATENT COOPERATION TREATY

## PCT

## INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference <b>970M 1412WOP</b>	<b>FOR FURTHER ACTION</b> see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.	
International application No. <b>PCT/ IB 97/ 01634</b>	International filing date (day/month/year) <b>17/10/1997</b>	(Earliest) Priority Date (day/month/year)
Applicant <b>ZAKRYTOE AKTSIONERNOE OBSCHESTVO "OSTIM" et al.</b>		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 2 sheets.

It is also accompanied by a copy of each prior art document cited in this report.

1.  Certain claims were found unsearchable (see Box I).
2.  Unity of invention is lacking (see Box II).
3.  The international application contains disclosure of a **nucleotide and/or amino acid sequence listing** and the international search was carried out on the basis of the sequence listing
  - filed with the international application.
  - furnished by the applicant separately from the international application,
    - but not accompanied by a statement to the effect that it did not include matter going beyond the disclosure in the international application as filed.
  - Transcribed by this Authority
4. With regard to the title,  the text is approved as submitted by the applicant
  - the text has been established by this Authority to read as follows:
5. With regard to the **abstract**,
  - the text is approved as submitted by the applicant
  - the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this International Search Report, submit comments to this Authority.
6. The figure of the **drawings** to be published with the abstract is:
  - Figure No. \_\_\_\_\_  as suggested by the applicant.
  - because the applicant failed to suggest a figure.
  - because this figure better characterizes the invention.

None of the figures.

## INTERNATIONAL SEARCH REPORT

International Application No

PCT/IB 97/01634

## A. CLASSIFICATION OF SUBJECT MATTER

IPC 6 A61K7/16

According to International Patent Classification(IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category <sup>o</sup>	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 786 245 A (SANGI CO., LTD) 30 July 1997 see the whole document ---	1-10
X	EP 0 664 133 A (AKTIONERNOE OBSCHESTVO ZAKRYTOGO TIPIA "OSTIM") 26 July 1995 see claim 1; example 1 ---	1
E	WO 98 18719 A (AKTSIONERNOE OBSCHESTVO ZAKRYTOGO TIPIA "OSTIM") 7 May 1998 see claims 1,14 -----	1



Further documents are listed in the continuation of box C.



Patent family members are listed in annex.

## ° Special categories of cited documents :

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search

Date of mailing of the international search report

9 July 1998

16/07/1998

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**INTERNATIONAL SEARCH REPORT**

Information on patent family members

International Application No

PCT/IB 97/01634

Patent document cited in search report		Publication date		Patent family member(s)		Publication date
EP 786245	A	30-07-1997	JP	9202717 A		05-08-1997
EP 664133	A	26-07-1995	RU	2077329 C		20-04-1997
			WO	9503074 A		02-02-1995
WO 9818719	A	07-05-1998		NONE		